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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,950	08/17/2000	Josef Burg	HUBR-1159	9456
24972	7590	04/22/2005	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			AUDET, MAURY A	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/555,950

**Applicant(s)**

BURG ET AL.

**Examiner**

Maury Audet

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 88-99, 101, 103 and 104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 88-99, 101, 103 and 104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

The amendment filed February 4, 2005 is acknowledged and has been entered. Claims 88-99, 101, and 103-104 remain examined on the merits. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102/103***

Claims 88-99, 101, and 103-104 stand rejected under 35 U.S.C. 102(b) and/or (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of the teachings of Watson et al. (Glycobiology, 1994), Takeuchi et al. (Proc. Natl. Acad. Sci., October 1989), Blumen et al. (US 5,459,031), Akamatsu et al. (US 4,745,099), and Strickland et al. (US 5,856,298) for the reasons set forth in the previous Office Action.

Again, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' claimed EPO composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the references (both CHO and HeLa), the burden of establishing non-obviousness by objective evidence remains shifted to the Applicants.

***Response to Arguments***

Applicant's new argument is that the references teaching production of EPO from CHO cells do not produce the same EPO compositions with the claimed N acetyl lactosamine amounts. Applicant's arguments have been considered, but are not found persuasive. It is noted in particular that Applicant himself originally claimed these same EPO compositions/

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lactosomine ranges could be produced from EITHER CHO cell lines (see now deleted step i) in claims 88, 89, and 101) or human cell lines (i.e. HeLa 1-4). Although this amendment (and corresponding argument) arguably constitutes a change of the invention as originally searched/examined, the Examiner continued with the examination of the claims on the premise that the EPO compositions were produced by CHO cells (or human cells, see i.e. Shoemaker, Treco et al., Descamps et al. I and II cited below in Citation of Pertinent Prior Art, as relevant to the latter but not necessary to be applied, since Applicant claimed that either CHO cells or human cells produced the same EPO compositions).

### ***Conclusion***

#### **Citation of Pertinent Prior Art**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In line with the references above, Takeuchi et al. #2 (Glycobiology. 1991 Sep;1(4):337-46. Review) also teach EPO from CHO cells, including repeating tetraantennary units (see e.g. Table I, CHOb; entire document).

Additionally, HeLa produced EPO is taught in Shoemaker (US 4,835,260A, see col. 3, lines 16-35), Treco et al. (US 5,641,670, see col. 39, lines 58-50 and col. 40, lines 9-15), Descamps et al. I (US 5,789,390, see col. 11, lines 10-13) and Descamps et al. II (Arch Dermatol. 1996 Oct;132(10):1207-11, abstract, see middle:

“In a second step, 2 HeLa cell lines transduced with an AAV harboring the erythropoietin complementary DNA and producing high amounts of erythropoietin in vitro were isolated.”)

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 04/13/05



CHRISTOPHER R. TATE  
PRIMARY EXAMINER